IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Art Unit	:	1634
Applicant	:	Daniel Henry Densham
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For	:	Polynucleotide Sequencing Using a Helicase

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Following is a summary of the rejections set forth in the Office Action dated November 26, 2004, with the applicant's comments.

I. Rejection of claims 7-22 under 35 U.S.C. §112, first paragraph, for lack of written description

A. **The specification provides an adequate written description of the claimed method of sequencing (claims 7-20 and 22). The specification conveys to one of ordinary skill in the art that the applicant was in possession of the claimed subject matter.**

1. Claims 1-5 as filed in PCT/GB/00/01290 (publication no. WO 00/60114), describe the method of claims 7-20 and 22. Claims 1-5 of PCT/GB00/01290:

Claim 1. A method for sequencing a polynucleotide, comprising the steps of:

(i) reacting a target polynucleotide with a helicase/primase enzyme, under conditions suitable for enzyme activity; and

(ii) detecting the interaction between the enzyme and a nucleotide on the target, by measuring radiation.

Claim 2. A method according to claim 1, wherein the radiation is electromagnetic.

Claim 3. A method according to claim 1 or 2, wherein step (ii) comprises using surface plasmon resonance.

Claim 4. A method according to claim 1 or claim 2, wherein step (ii) comprises using nuclear magnetic resonance.

Claim 5. A method according to any preceding claim, wherein the enzyme is immobilized on a solid support.

2. Page 1, lines 9-20, and page 2, lines 21-25, of the specification, describe the method of claims 7-20 and 22.

3. Page 7, lines 26-28: "DNA sequencing was conducted by the method described in WO-A-99/05315, using the apparatus shown there in Fig. 1, but using only one focusing assembly (5) for pulsing monochromatic light into the cell."

a. Fig. 1 of WO-A-99/05315 (which is of record) is a schematic illustration of polynucleotide sequence analysis using surface plasmon resonance (SPR) spectroscopy, and shows an SPR sensing system and fluidic cell (see page 14, lines 23-37, and page 15, lines 1-17, of WO-A-99/05315).

b. Further description of the exemplified method of the invention is provided in the subsequent paragraphs of pages 7 and 8 of the application.

c. The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661; 18 USPQ2d 1331, 1332 (Fed. Cir. 1991);

Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384; 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); *and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463; 221 USPQ 481, 489 (Fed. Cir. 1984).

B. The specification provides an adequate written description of the claimed chip (claim 21). The specification conveys to one of ordinary skill in the art that the applicant was in possession of the claimed subject matter.

1. Claim 6 as filed in PCT/GB/00/01290 describes the chip of claim 21:

   Claim 6. A sensor chip comprising a helicase/primase enzyme immobilized thereon.

2. Page 4, lines 22-24, of the specification describes the chip of claim 21.

II. Rejection of claims 7-22 under 35 U.S.C. §112, first paragraph, for lack of enablement

The method and chip of the claimed invention are reasonably enabled by the specification. One of ordinary sill in the art would be able to make and use the invention without undue experimentation. The fact that a technique that may be utilized to carry out the invention (SPR spectroscopy) was described in a previous publication (WO-A-99/05315) that was not incorporated by reference does not negate the enablement of the pending claims.

The subject matter disclosed in WO-A-99/05315 is not critical or essential to making or using the claimed invention. A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. §112. See *In re Mayhew*, 527 F.2d 1229, 1233; 188 USPQ 356, 358 (CCPA 1976). In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567; 191 USPQ 429, 431 (CCPA 1976). Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to

function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality. **MPEP 2164.08(c)**.

The reaction conditions and necessary starting materials are disclosed in the application, including the example at pages 7 and 8. Furthermore, it has been held that even if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. *In re Ghiron*, 442 F.2d 985, 991; 169 USPQ 723, 727 (CCPA 1971). The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981) and **MPEP 2164.01(b)**.

"It is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art. As was said in *Webster Loom Co. v. Higgins et al.*, ...the applicant 'may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings'." *In re Howarth*, 210 USPQ 689, 692 (C.C.P.A. 1981).

Not everything necessary to practice the invention need be explicitly disclosed in the application. *In re Buchner*, 929 F.2d 660, 661; 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) and **MPEP 2164.08**. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. §112 is satisfied. *In re Fisher*, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. §112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987) and **MPEP 2164.01(b)**. The specification need not even contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908; 164 USPQ 642, 645 (CCPA 1970) and **MPEP 2164.02**.